UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,585	12/20/2001	Terry Roemer	10182-016-999	8340

20583 7590 01/13/2004

JONES DAY
222 EAST 41ST STREET
NEW YORK, NY 10017

EXAMINER	
GUZO, DAVID	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,585	ROEMER ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/26/02.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-9, drawn to a method for constructing a strain of diploid fungal cells, classified in Class 435, subclass 484.

II. Claims 2-4, 6-9, drawn to a method of assembling a collection of diploid fungal cells, classified in class 435, subclass 489.

III. Claims 10-13, 53-55, drawn to a strain of diploid fungal cells, classified in class 435, subclass 254.11.

IV. Claims 14-21, drawn to a collection of diploid fungal cells, classified in class 435, subclass 254.2.

V. Claim 22-23, drawn to a nucleic acid molecule microarray, classified in class 536, subclass 23.1.

VI. Claims 24-25, drawn to a method for identifying a gene essential to the survival (or growth) of a fungus, classified in Class 435, subclass 6.

VII. Claim 26, drawn to a method for identifying a gene that contributes to the virulence and/or pathogenicity of a fungus, classified in Class 435, subclass 29.

VIII. Claim 27, drawn to a method for identifying a gene that contributes to the resistance of a diploid fungus to an antifungal agent, classified in Class 435, subclass 6.

IX. Claim 28, drawn to a method for identifying an antifungal agent, classified in class 435, subclass 254.11.

X. Claim 29, drawn to a method for identifying a therapeutic agent for treatment of a mammalian disease, classified in class 435, subclass 29.

XI. Claims 30-31, drawn to a method for correlating changes in the levels of proteins with the inhibition of growth or proliferation of a diploid fungal cell, classified in class 435, subclass 483.

XII. Claims 32-42, drawn to nucleic acid molecules encoding gene products from diploid fungal cells, classified in class 536, subclass 23.72.

XIII. Claim 43, drawn to a polypeptide selected from SEQ ID NO: 63-123, classified in class 530, subclass 350.

XIV. Claims 44-48, drawn to polypeptides, classified in class 530, subclass 350.

XV. Claims 49-51, drawn to a method of identifying a compound which modulates the activity of a gene product, classified in class 435, subclass 7.1.

XVI. Claim 52, drawn to a method of eliciting an immune response in an animal, classified in class 514, subclass 2.

XVII. Claim 56, drawn to a method of identifying a binding partner to a polypeptide, classified in class 435, subclass 7.31.

XVIII. Claims 57-59, drawn to a method for identifying a compound having the ability to inhibit growth or proliferation of Candida albicans, classified in class 435, subclass 29.

XIX. Claims 60-62, drawn to a method for inhibiting growth or proliferation of Candida albicans, classified in class 435, subclass 6.

XX. Claims 63-64, drawn to a method for manufacturing an antimycotic compound, classified in class 435, subclass 41.

XXI. Claims 65-70, drawn to a method for treating a patient for Candida albicans infection or inhibiting or preventing contamination of a surface by Candida albicans, classified in class 514, subclass 44.

XXII. Claims 71-72, drawn to an antibody, classified in class 530, subclass 387.1.

XXIII. Claims 73-74, drawn to a method for evaluating a compound against a target gene, classified in class 435, subclass 6.

XXIV. Claim 75, drawn to a method for identifying an antimycotic compound, classified in class 435, subclass 254.21.

XXV. Claim 76, drawn to a computer, classified in class 709, subclass 101.

XXVI. Claim 77, drawn to a computer assisted method for identifying essential genes of fungi, classified in class 702, subclass 20.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II, VI-XI, XV-XXI, XXIII-XXIV and XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve patentably distinct methods with each method directed to a patentably distinct outcome (i.e.

constructing a diploid strain of a fungus vs. identifying a virulence gene or an antimycotic compound, etc.) or involving unrelated method steps. A search of each method would not be co-extensive with a search of the others and would be burdensome. With regard to the restriction between Groups I and II, it is noted that a method of assembling a collection of diploid fungal cells, each with a different modified allele, is patentably distinct from a method of constricting a single strain of fungus because the outcomes are different and distinct, i.e. production of a single diploid fungus strain with a modified allele vs. a collection of different diploid fungal cells each with a different, unrelated, modified allele.

Inventions III-V, XII-XIV, XXII and XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions involve patentably distinct, unrelated biochemical molecules with distinct structures and functions (i.e. DNA vs. fungal proteins vs. antibodies) and compositions such as a computer (Group XXIII). A search of one would not be co-extensive with a search of the other and would be burdensome.

Inventions III-IV and VI-XI, XVIII, XIX and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case the diploid fungal cells of Groups III-IV can be used in any of the materially different methods of using said cells in Groups VI-XI, XVIII, XIX and XXIII.

Inventions XII and XV, XIX-XXI, XXIII-XXIV and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group XII can be used in any of the patentably distinct methods of using recited in Groups XV, XIX-XXI, XXIII-XXIV and XXVI.

Inventions III-V, XII, XIII, XIV, XXII-XXIII, XXV and VI-XI, XV-XXI, XXIII-XXIV and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups III-V, XII-XIV, XXII-XXIII, XV can be used in any of the processes recited in Groups VI-XI, XV-XXI, XXIII-XXIV and XXVI. For example, the diploid fungal cells of Groups III can be used to identify a gene that contributes to virulence (Group VII), or can be used to identify a gene that contributes to resistance of a fungus to an antifungal agent (Group VIII), etc. Also, the polypeptide products of Group XIV can be used in a method of identifying a binding partner (Group XVII) or in a method of eliciting an immune response in an animal (Group XVI), etc.

Inventions I-II and III-IV are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f). In the instant case the diploid fungal cells of group III or the collection of diploid fungal cells can be made by a non-recombination based method, i.e. by direct insertion of sequence cassettes in the relevant genes targets.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions involve a method for making a single diploid fungal strain with a specific alteration in a specific gene (Group I) whereas Group II involves making a collection of hundreds of different diploid fungal strains each unrelated to the other. The manufacture of a collection of different fungal cells each with an unrelated genetic alteration is patentably distinct from a method of making a single strain. Additionally, it would be a significant search burden to search each of the hundreds of different sequences encompassed by the claims.

With regard to the restriction between Groups III and IV, a single strain of a diploid fungus with a modified allele is patentably distinct from a collection of hundreds of different diploid fungal strains each with a different unrelated modification in a different gene. Likewise a microarray of hundreds of different nucleic acid sequences (Group V) is patentably distinct from any given single nucleic acid sequence (Group XII)

claimed. If applicants elect any of the compositions of Groups III or XII or XIII or XIV or XXII or XXV or any of the methods of Groups I, VI-XI, XIV, XV, XVI, XVII, XVIII-XXI, XXIII, XXIV and XXVI, a further election of a single nucleotide or amino acid is required because each of said sequences is a patentably distinct sequence independent of, and distinct from, any other sequence in the list of sequences claimed. A search of all the recited sequences would be burdensome. With respect to restriction between different nucleic acid or amino acid sequences, the following is noted. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

It is further noted that if applicants elect the subject matter of Group II, a further election of up to TEN sequences is required. If applicants elect the subject matter of Groups IV or V, applicants are requested to suggest a sequence or sequences which

applicants believe are novel for preliminary searching by the Office since a given collection of nucleic acid sequences is rendered novel by any single novel sequence in said collection (See MPEP 803.04).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. After January 14, 2004, the examiner can be reached at (571) 272-0767. The examiner can normally be reached Monday-Thursday at 8:00 AM - 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVID GUZO
PRIMARY EXAMINER

David Guzo
January 12, 2004